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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,191

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Deborah E. Wilson

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KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE #1600
PORTLAND, OR 97204-2988

EXAMINER

SMITH, JENNIFER A

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,191	Applicant(s) WILSON ET AL.	
	Examiner JENNIFER A. SMITH	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/26/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24 and 33-41 is/are rejected.
- 7) ☒ Claim(s) 25-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/2009 has been entered.

Claims 1-23 and 42 are canceled.

Claims 24-41 have been are pending and are presented for examination.

37 C.F.R. 1.132 Declaration

The declaration submitted under 37 CFR 1.132 filed 08/26/2009 is sufficient to overcome the rejection of claims 24-41 under 35 U.S.C. 102(b) based upon a public use or sale of the invention. The declaration has been signed by the inventor and attests "that the PowerPoint presentation disclosed and described in the Declaration executed by the inventors and filed with the Office on February 24, 2009, was a reproduction of an internal, private, PowerPoint presentation conducted by the inventors at the National Institutes of Health (NIH) prior to the effective filing date of Nelson et al., (already of record)". The internal, private, research meeting was attended by Dr. Wilson and an internal scientific review group of invited NIH personnel. Applicants submit that the private and confidential meeting during which the presentation was made was not

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public, and that the inventors restricted the information, and location to where there was a reasonable expectation of privacy" is required to support the attestation alluded to the applicant's representative.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24 and 33-37, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al. (US Patent No. 6,156,267).

In regard to claims 24, 39, and 40 the Pai reference teaches an apparatus for sterilization. The apparatus contains a storage tank (1) and an anti-microbial chlorine dioxide source [See Column 6, lines 3-15] (3) [See Figure 1]. The sterillant inlet (2) and outlet (5) valves demonstrate the chamber is sealable. The apparatus contains a

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control device which monitors humidity and pressure [See Column 3, first paragraph].

The apparatus forms a pre-vacuum type sterilizer and a vacuum pull will result when there is no air in the device [See Column 13, lines 37-50].

The reference fails to explicitly disclose a humidifier in fluid contact with the anti-microbial gas source, nor does the reference teach a vacuum generator.

The Pai reference teaches a system for controlling the humidity and pressure [See Claim 1] and it necessarily follows that the apparatus would contain a humidifier and a vacuum generator. One of skill in the art would recognize the need to utilize a humidifier device and a vacuum generating device to meet the control aspects taught in the Pai reference.

In regard to claims 33 and 39, Pai et al. teach decontamination with chlorine dioxide in gaseous form [See Column 6, lines 7-16]. One of skill in the art would recognize the need to provide chlorine dioxide generator as a means to provide gaseous chlorine dioxide.

In regard to claim 34, Pai et al. teach a chamber (1) surrounded by chamber walls (7).

In regard to claims 35-37, Pai et al. teach a control system which measures and adjusts processing parameters such as temperature, pressure, relative humidity, and anti-microbial agent concentration. The control system provides real-time control of critical parameter levels within the device [See Column 3, lines 7-13]. One of skill in the art would recognize a heat source and hygrometer for regulating humidity are integral parts of the system described in the Pai reference. The real-time controls monitor and send feedback to the decontamination system with respect to heat and humidity and a heater and hygrometer are necessary components for regulating these values.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pai et al. (US Patent No. 6,156,267) in view of Kochte (US Patent No. 5,439,654).

In regard to claim 38, the Pai reference does not teach an autoclave or hypobaric chamber.

The Kochte reference is drawn to a countertop decontamination unit which can take place in an oven autoclave [See Column 1, lines 42-44].

One of ordinary skill in the art, at the time of Applicant's invention, would have been motivated to use an autoclave as the decontamination chamber because medical, dental, surgical, veterinary, and laboratory equipment and instruments have often been

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sterilized in a steam autoclave. Autoclaves kill life forms with a combination of high temperature and pressure [See Column 1, lines 29-33].

Allowable Subject Matter

Claims 25-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The closest prior art on record – Pai et al. teaches the apparatus for sterilization but fails to teach the organization of the fluid flow paths like those claimed in the present application. Furthermore, one of skill in the art would not have been motivated to position the humidifier, gas source, vacuum generator, and decontamination chamber in the arrangement as claimed in the present apparatus claims.

Conclusion

Claims 24 and 33-41 are rejected.

Claims 25-32 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. SMITH whose telephone number is (571)270-3599. The examiner can normally be reached on Monday - Friday, 9:30am to 6:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorgengo can be reached on (571)272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.A. LORENZO/
Supervisory Patent Examiner, Art Unit 1793

Jennifer A. Smith
November 23, 2009
Art Unit 1793

JS